

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC.,)	
)	
Plaintiff,)	
)	
v.)	C. A. No. 21-1615 (MN)
)	
LUPIN LIMITED,)	
)	
Defendant.)	

**STIPULATION AND ORDER TO STAY
AND BE BOUND BY RESULT IN LITIGATION**

This Stipulation is made by and between (1) Plaintiff Gilead Sciences, Inc. (“Plaintiff”) and (2) Defendant Lupin Limited (“Defendant”).

WHEREAS, Defendant submitted Abbreviated New Drug Application (“ANDA”) No. 216511 (“SYMTUZA ANDA”), seeking approval to manufacture, use, offer for sale, sell, and/or import a generic version of third party Janssen Products, L.P.’s SYMTUZA[®] product, containing a four-drug combination of darunavir, cobicistat, emtricitabine, and tenofovir alafenamide (“TAF”);

WHEREAS, Plaintiff owns patents listed in the Orange Book for SYMTUZA[®], including U.S. Patent Nos. 8,754,065 (the “’065 Patent”) and 9,296,769 (the “’769 Patent”), which relate to a hemifumarate form of TAF (collectively, the “TAF Hemi Patents”);

WHEREAS, Plaintiff brought suit against Defendant in this case (the “SYMTUZA TAF Action”) on November 15, 2021, alleging infringement of the TAF Hemi Patents;

WHEREAS, Plaintiff previously brought suit against Defendant in *Gilead Sciences, Inc. v. Apotex, Inc. et al.*, 1:20-cv-00189-MN (D. Del.) (the “TAF Action”) on February 7, 2020, alleging infringement of four patents, including the TAF Hemi Patents, based on Defendant’s submission

of ANDA Nos. 214226, 213926, and 214227, seeking approval to manufacture, use, offer for sale, sell, and/or import generic versions of Gilead's TAF-containing products, VEMLIDY[®], DESCOVY[®], and ODEFSEY[®], respectively;

WHEREAS, Plaintiff and Defendant agree that the infringement and validity issues regarding the TAF Hemi Patents in this SYMTUZA TAF Action and the TAF Action are substantially the same;

WHEREAS, Plaintiff alleges in this SYMTUZA TAF Action that Defendant's submission of its SYMTUZA ANDA infringed claims 1, 6-19, 23, 26, 30 of the '065 Patent and claims 1-5, 7-12, 15, 17 of the '769 Patent (collectively, the "Asserted Claims") under 35 U.S.C. § 271(e)(2), and upon approval and sale in the United States, Defendant's SYMTUZA ANDA product would infringe the Asserted Claims under 35 U.S.C. §§ 271(a), (b), and/or (c);

WHEREAS, Lupin acknowledges that under the Court's Claim Construction Order in the TAF Action (D.I. 236), its SYMTUZA ANDA product, upon approval and sale in the United States, would infringe the Asserted Claims;

WHEREAS, with respect to Defendant's SYMTUZA ANDA provided to Plaintiff's counsel on November 8, 2021 pursuant to the parties' Offer of Confidential Access and Defendant's SYMTUZA ANDA product as reflected in such SYMTUZA ANDA, Plaintiff agrees that it will not assert infringement of claims 2-5, 20-22, 24-25, 27-29 and 31 of the '065 Patent or claims 6, 13-14, 16, and 18-19 of the '769 Patent, but Plaintiff reserves the right to assert infringement of these claims based on changes made to Defendant's SYMTUZA ANDA and SYMTUZA ANDA product;

WHEREAS, Plaintiff and Defendant have agreed to stay this SYMTUZA TAF Action to streamline the resolution of the infringement and validity issues with respect to the TAF Hemi Patents and thereby conserve party and judicial resources;

WHEREAS, the parties have agreed that Plaintiff and Defendant shall be bound, in accordance with the terms explained hereafter, by any final judgment on the merits in the TAF Action concerning the TAF Hemi Patents; and

WHEREAS, Plaintiff and Defendant agree that by making this joint stipulation, neither party shall be deemed to have delayed this SYMTUZA TAF Action.

NOW THEREFORE, Plaintiff and Defendant, by and through their respective undersigned counsel, hereby stipulate and agree as follows, subject to approval by the Court:

1. Defendant's submission of its SYMTUZA ANDA infringed the Asserted Claims under 35 U.S.C. § 271(e)(2), and Defendant's making, using, selling, offering for sale, and/or importation of its SYMTUZA ANDA product in the United States would infringe the Asserted Claims under 35 U.S.C. §§ 271(a), (b), and/or (c).

2. This SYMTUZA TAF Action will be stayed in its entirety until such time as final judgment (whether on the merits or otherwise) is entered by this Court as between Plaintiff and Defendant concerning the TAF Hemi Patents in the TAF Action.

3. If the TAF Action as to the TAF Hemi Patents is resolved by settlement or any other type of stipulated consent, or otherwise agreed final judgment as between Plaintiff and Defendant, prior to the entry by this Court of a final judgment following actual litigation on the merits concerning the TAF Hemi Patents, Plaintiff and Defendant agree as follows:

a. The stay of this SYMTUZA TAF Action shall be lifted upon the request and motion of either party;

b. Any and all fact or expert discovery taken or elicited in the TAF Action can be used in this SYMTUZA TAF Action;

c. There will be no additional fact discovery in this SYMTUZA TAF Action;

d. If expert discovery has been completed in the TAF Action, there shall be no additional expert discovery in this SYMTUZA TAF Action related to the infringement or validity of any claim of the TAF Hemi Patents; and

e. The agreements in Paragraphs 3(c) and 3(d) are made based on Defendant's SYMTUZA ANDA provided to Plaintiff's counsel on November 8, 2021 pursuant to the parties' Offer of Confidential Access and Defendant's SYMTUZA ANDA product as reflected in such SYMTUZA ANDA. Plaintiff reserves the right to seek additional discovery based on any changes made to Defendant's SYMTUZA ANDA and SYMTUZA ANDA product.

4. If a final judgment following actual litigation on the merits is entered by this Court as between Plaintiff and Defendant in the TAF Action regarding the validity and infringement of the Asserted Claims of the TAF Hemi Patents (which does not include a judgment that is entered as a result of settlement, consent judgment, stipulated judgment, or other judgment or disposition that is not an actual contested decision on the merits), the parties agree that the same judgment shall be entered in this SYMTUZA TAF Action with respect to Defendant's infringement and the validity of the Asserted Claims of the TAF Hemi Patents.

5. Plaintiff and Defendant maintain, and neither party hereby waives, nor shall this stipulation affect, the right of either party to appeal this Court's claim construction ruling in the TAF Action (D.I. 236) and/or any subsequent judgment regarding the validity of the Asserted Claims of the TAF Hemi Patents once a final appealable judgment is entered.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
jtigan@morrisnichols.com

Attorneys for Plaintiff

March 2, 2022

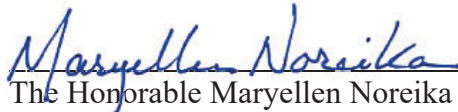
PHILLIPS McLAUGHLIN & HALL, P.A.

/s/ David A. Bilson

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pmhdelaw.com
dab@pmhdelaw.com

Attorneys for Defendant

SO ORDERED this 4th day of March 2022.



The Honorable Maryellen Noreika
United States District Judge